MAR 2 6 2014 K132759

5. 510(K) SUMMARY

Acc. to 807.92

Applicant's Name and Address:	Dolphys Medical B.V. De Lismortel 31 Eindhoven 5612AR The Netherlands
Contact Person:	Ms. Fabienne Peters Head QAC/RA Phone: +31 40 7516020 +31 40 7516022 (direct)
Applicants US Contact Person:	**Not yet appointed**
Date submission was prepared:	23 Dec 2013
Device Name: Trade name: Common	Ventrain
Name: Classification	Ventilator
Name:	21 CFR 868.5925, Powered emergency ventilator; Product code **BTL**, ventilator, emergency, powered (resuscitator)
Class:	2

Device Description:
Ventrain is a manually operated ventilation device that provides adequate ventilation through a narrow-bore transtracheal catheter, even in case of a completely obstructed upper airway. Ventrain is specifically designed for 'cannot intubate, cannot ventilate' emergencies where conventional ventilation by mask and/or large-bore endotracheal tube cannot be performed.

Ventrain consists of a handheld unit for manual control of gas flow to the patient. One side of the handheld is connected with an oxygen supply, such as an oxygen cylinder. The other side of the handheld is connected to a transtracheal catheter inserted in the patient.

The handheld contains a polymer manifold for channeling the gas flow through the device. The user controls ventilation by opening or closing holes in the manifold with the thumb and index finger.

Ventrain is capable of actively removing gas from the lungs in the expiration phase by suction (Expiratory Ventilation Assistance). Therefore, Ventrain can also be used for patients with a complete upper airway obstruction

Intended use:
For emergency ventilation via a small lumen transtracheal catheter, in case conventional ventilation by mask and/or a large-bore endotracheal tube cannot be performed. Ventilation is

accomplished by manual, intermittent ventilation with oxygen through the catheter for subsequent lung inflation and deflation.

Legally marketed devices to which substantial equivalence is claimed:

510(k) Number	Device Name
K112783	ManuJet III

Substantial Equivalence:
Ventrain and the predicate device were compared on the following aspects:

- Intended Use
- Intended patient population
- Intended use environments
- Operating principle, energy source
- Gas supply
- Patient connections
- Performance specifications such as frequency, minute volumes, I:E ratio
- Ambient conditions

With respect to the operating principle, the difference between both devices is that Ventrain provides (assisted) expiration through the device whereas the predicate device has no such functionality and therefore requires a partially open airway for expiration. As a result, a fully blocked airway is no contra indication for Ventrain and Ventrain can be used with a broader patient population compared to the predicate device. Further analysis showed that the expiration functionality did not introduce new risks

With respect to performance specifications, maximum minute volumes are lower with Ventrain than with the predicate device. Literature showed that this smaller range of minute volumes possible with Ventrain is still sufficient for its intended use.

On all other aspects, there were either no differences or differences found were deemed not clinically significant.

From the comparison with the predicate device and the discussion of specific differences, it was concluded that:

- Ventrain has the same intended use as the predicate device
- Differences between both devices do not raise new questions of safety and effectiveness
- Ventrain is at least as safe and effective as the predicate device

Summary of Performance Testing:
Ventrain passed a series of tests that demonstrate that the device is capable of performing to its stated Intended Use in its intended environments.

Qualification included performance testing as per 1S010651-5 standard, hazard analysis conform the IS014971standard and system level verification and validation tests.

All gas conducting parts were found to be biocompatible in accordance with ISO 10993-1:2009 Biological Evaluation of Medical Devices – Part 1: Evaluation and testing

The results of all verification and validation testing demonstrate that all system and design requirements for the Ventrain device have been met.

Summary of Clinical testing
Clinical testing was not required to demonstrate substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 26, 2014

Dolphys Medical B.V.
Ms. Fabienne Peters
De Lismortel 31
Building Caralyst
Eindhoven, Netherlands
5612 AR

Re: K132759
Trade/Device Name: Ventrain
Regulation Number: 21 CFR 868.5925
Regulation Name: Powered emergency ventilator
Regulatory Class: Class II,
Product Code: BTL
Dated: December 23, 2013
Received: December 26, 2013

Dear Ms. Peters:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiolgoy, General Hospital,
Respiratory, Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number	K132759
Device Name	Ventrain
Indications for Use	For emergency ventilation via a small lumen transtracheal catheter, in case conventional ventilation by mask and / or a large-bore endotracheal tube cannot be performed. Ventilation is accomplished by manual, intermittent ventilation with oxygen through the catheter for subsequent lung inflation and deflation.

Prescription Use __X__ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 subpart D) (Part 21 CFR 801 subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anya C. Harry -S
2014.03.26
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